K051840

AUG 15 2005

510(k) Summary for Public Disclosure

Submitter: St. Jude Medical, Inc
Endocardial Solutions
1350 Energy Lane, Suite 110
St. Paul, MN 55108 USA
Phone: 651-523-6900
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Contact: Karen J. McKelvey
Regulatory Compliance Engineer

Date Prepared: May 23, 2005

Trade Name: EnSite Verismo

Common name: Electrophysiology cardiac mapping system

Classification Name: System, Image Processing, Radiological (21 CFR 892.2050)

Predicate Device: Vital Images, Inc – Vitrea®2

Device Description: The EnSite Verismo™ Segmentation Tool is designed to function on the EnSite System's display workstation. This software tool allows importation of DICOM slice data from a variety of CT and MRI manufacturers. Once imported into the EnSite System, this slice data can be segmented into a 3D surface model. This model can be displayed during EP studies conducted on the EnSite System.

Intended use: The EnSite Verismo™ Segmentation Tool (EV 1000) is indicated for use in generating 3D models from slice-bases

	DICOM3 image data. Generated models are intended to be displayed on the EnSite® System.
Technological Characteristics:	The new device has the same technological characteristics as the legally marketed predicate device.
Non-clinical Performance Data:	The EnSite Verismo Software underwent a battery of bench and user tests. Device validation testing was conducted in accordance with in-house procedures.
Conclusion:	An evaluation of new software EnSite Verismo indicates that the device is as safe and effective as the previously marketed device to which it is being compared and does not raise any new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2005

St. Jude Medical, Inc.
Endocardial Solutions
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K051840
Trade/Device Name: EnSite Verismo™ Segmentation Tool (EV1000)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 2, 2005
Received: August 3, 2005

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051840

Device Name: EnSite Verismo™ Segmentation Tool (EV1000)

Indications For Use:

The EnSite Verismo™ Segmentation Tool (EV 1000) is indicated for use in generating 3D models from slice-based DICOM3 image data. Generated models are intended to be displayed on the EnSite® System.

Prescription Use __X__ ~~AND~~/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Kessler

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051840